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George H. Martin Jr.

Indiana University School of Law

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Informed Consent and Medical Experimentation

GEORGE H. MARTIN, JR.

Certain biomedical technologies already or almost already with us “threaten to reduce the meaning of man and to degrade the human spirit in the very process of becoming technologically feasible, long before the final stage of deployment and widespread use has been reached.”¹ It is this threat that has prompted me to consider certain medical and legal problems associated broadly with the human experimentation process. I shall be examining the concept of “informed consent” to both experimental medical therapy and nontherapeutic scientific experimentation as a means of protecting man from the potential ravages of a zealous application of scientific advances in the biomedical sphere. The problems surrounding human experimentation seem to be an especially fruitful area for research, for they starkly present the tensions between two fundamental values of Western civilization: the protection of individual inviolability and the freedom of scientific inquiry.² Where values conflict and competing policies vie for public attention, acceptance, and funding, then the law is often called upon to mediate the ensuing conflicts. We shall examine the role that law can effectively play in the human experimentation process.

In this time of rapidly accelerating technological development and innovation, one often hears cries that “Technology is out of control!” The posed solution is generally that we must “retrench,” that man himself must take an active and firm role in rationally planning the future development of technology by considering both social and individual benefits and costs, alternative modes of development, etc. This may be a correct approach, as far as it goes. The focus on man as decision-maker is correct. However, the problem only *begins* and does not *end* here. We must ask who the decision-maker is, can be, and should be in human experimentation situations, determine his capacity for decision-making, and analyze the availability of alternative safeguards should informed consent prove to be a faulty one.

In the context of human experimentation, we find that the concept of “informed consent” has been accepted as the *sine qua non* for research with human beings. Hence, courts, commentators, and scientists have seen protection for man from undesirable biomedical technologies as emanating from requirements of the definition

of informed consent and well-considered applications of that doctrine in specific circumstances.

I suggest in this paper that the effort to protect human subjects through the doctrine of informed consent is a seriously misplaced, and therefore dangerous, one, for by deluding ourselves into thinking that consent can be an adequate safeguard for men, we fail to look for other, much more significant mechanisms to protect both the human and scientific values that Western civilization professes to value so highly. Consequently, my effort here will be threefold: to examine the functions, weaknesses and limitations, and alternatives to the doctrine of informed consent as it is applied as a protective device for subjects in the human experimentation process. I shall also consider the current state of the law on informed consent and suggest that subject/patient protection in the biomedical context can perhaps best be effected by a comprehensive look at the whole process of experimentation and not simply focus on the administrative stage as informed consent does.

THE EXPERIMENTATION PROCESS

Therapy and Experimentation

Over two hundred years ago a court of law held that a physician experiments at his peril, that if he deviates in any way from the commonly accepted method of medical treatment for his patient, he is liable for the consequences that ensue.³ Not surprisingly, this view has altered somewhat over the course of the past two centuries. While traditionally medical “treatment” and “experimentation” have been seen as two separate entities, the more sophisticated medical view today is that all therapy—at least all serious therapy—is experimentation, but that all experimentation on human subjects does not necessarily carry any therapeutic benefit to the patient or subject. This distinction is worth keeping in mind. As Paul Freund has stated:

The deepened knowledge of complex biological processes, the range of options in treatment, and the idiosyncrasies of patients’ reactions, all **make** it inevitable that sound medical practice be experimental in a sense that does not contradict the nineteenth-century admonition, but **renders** it much less meaningful and serviceable as a guide to professional conduct.⁴

There is as well an interrelation between therapy and systematic scientific investigation that has also aided medical science in becoming more experimental today. This relationship is founded on two very basic characteristics that underlie the origin of and growth of science and technology: “the need to control the workings of nature for our welfare and the simple, irreducible need to understand the world about us and ourselves.”⁵ It is thus argued (and with some force) that the need to acquire knowledge for the benefit of both individuals and society as a whole requires experimental interventions into the lives of patients/subjects. If the premise be granted, we must as well note countervailing motivations with equally deep roots in the nature of man and his society: that man fears the unknown and desires to perpetuate the status quo, that he places supreme value on the sanctity and dignity of the individual person, and that he deeply desires to control those decisions affecting his life, rather than leave them solely to the “experts.”⁶ As we shall see, it is this tension between the delegation of authority to experts and the concept of self-determination that frames the problems with informed consent that I will be discussing herein. Thus, given the internal logic and momentum of science

and technology, the quest of the scientific community to discover and to apply, and the impact of the basic concept of “progress” prevalent in the West since at least the time of the Enlightenment, it is appropriate at this stage to raise a fundamental question concerning the capacity of man to assert control over science and technology in general and human experimentation in particular and the extent to which the process can rationally be controlled.

As lawyers we have a particular concern with and perspective from which we view the whole problem of medical experimentation with human subjects.⁷ We tend to look to the fiduciary relationships involved, with the focus on the obligation of full disclosure and explanation by the investigator and the limitations of consent by the patient/subject. In fact, the traditional function of consent in the medical context was to differentiate between those interventions that were legally permissible and those that would subject a physician to liability for unauthorized experimentation on his patients.⁸ Yet we also recognize that we simply cannot look at consent as the definitive answer to questions of experimentation, for it is well established by both cases and commentaries that there are some instances in which a person will *not* be allowed to consent to certain procedures or actions, whether for his own or society’s benefit. Consent will at times be overridden to prevent experimentation of a particularly disagreeable sort. There are, in addition, circumstances in which a person’s lack of consent will be ignored as society strives to protect, again, either that particular individual from the consequences of his own actions or its own considered interests from the effects of his failure to consent to urgently needed medical care or to particularly important experimentation. These latter observations merely reflect the underlying question as to when a society, either actively or by acquiescence, may expose some of its members to harm in order to seek benefits for them or for society as a whole.⁹

Society and the Individual

Then again, it is also true, as a general principle, that society approves of a vast array of activities to which competent individuals may consent that have great social value but also entail varying degrees of probable harm to the individual: driving an automobile, coal-mining, sky-diving, etc. Calabresi expresses the rationale thus:

[W]e have become accustomed to the fact that many activities are permitted, even though statistically we know they will cost lives, since it costs too much to engage in these activities more safely or to abstain from them altogether. We have grade crossings, even though we know that with grade crossings a certain number of people will be killed each year and even though grade crossings could be eliminated relatively easily. We use automobiles—knowing that they cost us fifty thousand lives each year—because to use safer, slower means of transport would be far too costly in terms of pleasure and profits foregone. Worse even than that, we use automobiles with relatively safe (but relatively dangerous) control systems, and so on *ad infinitum*. And we do this because we deem the lives taken to be cheaper than the costs of avoiding the accidents in which they are taken.¹⁰

Calabresi’s tort analysis does inject the whole question of accident compensation and insurance into the medical experimentation context, and certainly the law can

and perhaps should respond with some thought to the application of his ideas to medical experimentation, but of course not without examining the implications of them for the safety of subjects involved and quality of experiments undertaken. For this in truth is our fundamental concern.

Calabresi argues for a system in which the actual choice over the taking of lives (should it come to that . . .) is as diffuse as possible:

Thus, the question remains as to whether or not we can find a control system in the medical experiment field that affords an adequate balancing of present against future lives and is still sufficiently indirect and self-enforcing as to avoid clear and purposive choices to kill individuals for the collective good.¹¹

The indication is that a serious look at randomness as a moral principle may be in order.¹²

Random selection would be a very significant procedural protection that could conceivably reinforce any substantive safeguards we can find in the informed consent doctrine. There are very real limitations of informed consent and the legal focus may now best be shifted from a reliance on consent to other forms of control in order to protect medical subjects. Note that I am not saying that the consent doctrine is useless or irrelevant in the experimentation process. The thrust of my paper is that in the medical experimentation context, the biggest problem we have with "consent" is that we have allowed it to seduce us into believing that we have been protecting people and we have not really developed *other* safeguards. If "consent" is then considered to be a "sham," one comes to the stark realization that there may in fact be precious little protection for human subjects at all. And *that* situation is a proper concern of society as a whole, not just the lawyers.

Law and Values

It might be asked here whether questions as to the sort of control system in medical experimentation ultimately to find societal acceptance reflect the sort of problems that traditional legal analysis has always confronted, or whether medical experimentation is different in kind from other activities that lead to legal problems? I would argue the former, although I would qualify it to the extent of acknowledging that medical experimentation involves a series of incredibly complex value questions that do not alter the nature of the basic legal problem but do make it harder to grapple with than most legal problems.¹³ If we accept the view of Hans Jonas that ". . . the *ultima ratio* of communal life is and has always been the compulsory, vicarious sacrifice of individual lives," that ". . . something sacrificial is involved in the selective abrogation of personal inviolability and the ritualized exposure to gratuitous risk of health and life, justified by a presumed greater, social good,"¹⁴ then it would seem that medical experimentation is not really different in kind from other legal problems.

Rather, like other legal problems, it involves a measuring and balancing of trade-offs, a weighing of risks, costs, and benefits that will best conform to the desires and expectations of the society within which the particular legal system operates. This is why I find Paul Freund's observation so relevant in the experimentation context: "The law is dialectic in a deeper sense than its adversary process. It mediates most significantly between right and right."¹⁵ For what we

are concerned with in experimentation is a balancing, a mediating between the legitimate rights of the various participants in the process, all of whom have unique, conflicting motivations, capacities, and value preferences—among them, the protection of man, the advancement of science, and the improvement of the well-being of society and of future generations.

Thus, only until we examine medical experimentation within the larger societal context can we begin to formulate the proper rules and procedures that will minimize harm and yet not erect great barriers to the acquisition of knowledge.¹⁶ And before this can be done we must perhaps first reject the notion that there is one natural ordering of ethics, that any one set of ethical norms is entitled to supremacy above all others, *e.g.*, “respect for human life.” This involves an “affirmation that the merits of the individual case determine the ascendancy of particular ethics for that particular case. If the assumption is granted that science is a part of the social system, an institution with values and norms not inherently superior to others, then ethical conflicts are inevitable.”¹⁷ This then should clear the way for examining each case of medical experimentation on its merits, rather than futilely trying to plug a case instantly into one particular ethical box. By deciding each case on its merits, it will be evident, as Vaughan indicates, that a particular ethic *then* will be made ascendant. But it is not argued here that there is any one particular, universal ethic that should control in all decision-making situations.¹⁸

CONSENT IN HISTORICAL PERSPECTIVE

Codes

Generally speaking, those involved in human research and medical experimentation are quite unlike the theoretical scientists who are, by and large, free to pursue their own research studies. In fact, the inquiries of the theoreticians are normally accepted, if not demanded by contemporary society. One major difference between the two groups of investigators appears to be that human researchers often find their scientific “freedoms” circumscribed by the rights and interests of their patients/subjects. In order for researchers to take proper account of these other rights and interests, it becomes important to define the nature and extent of their authority.¹⁹ The first question then to be faced is whether it is safe to leave total authority to the experimenter, trusting to the standards of his professional conscience. The experience of Nazi Germany suggests that it is not. For it should be clear that whenever subjects are too helpless or ignorant to resist participation in experiments, the investigator is in a position to pursue his scientific interests limited only by his own conscience and professional values.²⁰ It is to this particular problem that the various professional and ethical codes and standards adopted over the past thirty years particularly have been addressed.

The concept of informed consent for medical investigations was most strongly set forth in the famous Nuremberg Code of 1947 which was adopted by the U.S. Military Tribunal there as a standard for judging twenty-five German scientists accused of atrocities.²¹ While that particular code was drafted for the purpose of trying Nazi war criminals and did not necessarily answer all experimental questions, it has had a very great impact on the development of subsequent ethical codes adopted by international and national professional medical groups.²²

Perhaps second only to the Nuremberg Articles in worldwide influence is the Declaration of Helsinki (1964) of the World Medical Association.²³ It establishes a fairly complete ethical code for medical experimenters conducting clinical research. It also makes an important distinction between a purely scientific experiment and an experiment for therapeutic purposes, carried out on a doctor's own patient(s) whose illness is not responding to conventional medical treatments. Significantly, higher standards for obtaining consent are set for the nontherapeutic experiments.²⁴

Perhaps the Helsinki Code's greatest failing is that it focuses entirely on the needs of the individual subject and virtually ignores the interests of society—a charge that may fairly be leveled at most codifications and declarations. The only reference to “society” is the opening sentence: “It is the mission of the doctor to safeguard the health of the people.” The Code is therefore internally contradictory, setting up a double ethical charge for the investigator but giving him little guidance as to how to solve the inevitable conflict between the individual patient and the needs of society. The resolution of the moral dilemma simply does not yield to an application of a code.²⁵ Its existence may even be counterproductive if it serves to mask or obscure fundamental problems behind a facade of very general principles that may prevent rather than stimulate frank and open discussion of those basic ethical problems.

It has been suggested that in addition to informed consent, a “more reliable safeguard for an ethical approach to experimentation is provided by the presence of an intelligent, informed, conscientious, compassionate, responsible investigator.”²⁶ Yet it is not clear that medical science can or does produce such investigators.²⁷ One should note that with the traditional physician's view of responsibility for his patient's well-being it was easy to view the doctor as the sole decision-maker in the medical context. But once the physical benefits are viewed in relation to the patient's total situation, then Katz suggests that the patient himself may have to be given a greater role in the decision-making process.²⁸ This leads us directly to an analysis of the informed consent doctrine itself. If we grant that it is important for decision-makers other than the investigator to participate in the process, then it is imperative that we consider the subject's role. To determine this we need to examine the extent and limits of his ability to make decisions in his own behalf.²⁹

Consent as a Protective Device

With the concept of consent, we seem to be emphasizing that the primary regulation of the experimenter-subject relationship is to be between two of the three parties to the treatment/experiment. Consent has traditionally been thought to be a protection for subjects from physical violation of their bodily integrity and a formal recognition of the dignity of man, as an individual, as an *end* in himself. As a protective device, however, it is possible that consent may only protect a patient's freedom of choice (*i.e.*, the “right to consent”) and not much of anything else. Though consent looks at the experimentation process from the subject's perspective, the doctrinal content of consent may force us to examine the experimenter as well. For example, if the consent is to be “informed,” then we focus on (1) what the subject knew or (2) what the experimenter told the subject. The second focus is more directly on the actions of the experimenter than on those of the subject.

If we view consent as a protective device for the subject from his point of view, then the next logical question is: Did the experimenter go too far? Did he go

beyond the consent given so as to be liable for malpractice (whether under a battery or negligence theory)?³⁰ The same question could as easily be asked in a different way: How much did the subject consent to? Such questions inevitably lead to other inquiries into how the consent was obtained and whether there should be limits on what subjects can consent to.

These inquiries are important, for in speaking of consent we deal with a concept that is at the heart of Western civilization's idea of individual freedom. Such freedom is both protected and fostered through the law. It has been suggested that "[T]he requirement of consent is the primary means for implementing the abstract notion of self-determination."³¹ But the sense in which consent actually promotes freedom is more in the sense of permitting one to give up one's freedom than in protecting it. Little concern has been given to the former, and much to the latter in the medical experimentation context. While we emphasize tort law's protections against interventions to which one has not consented, we fail to observe that consent to certain actions that may lead to harm will prevent a recovery one otherwise would have had: *volenti non fit injuria* (to one who is willing, no wrong is done). Generally, where no public interest is contravened, courts have left the individual to work out his own destiny, and have not been concerned with protecting him from his own folly in permitting others to do him harm. In the negligence field, this policy is implemented through the doctrine of "assumption of risk" which relieves a defendant of an obligation to exercise due care (as an "affirmative defense") and prevents a plaintiff from recovering damages for resulting harm. Assumption of risk is utilized to say (1) that the risk that plaintiff assumed was unreasonable (*i.e.*, he was "contributorily negligent") or (2) that defendant was not negligent at all because he owed plaintiff no duty (negates the existence of a tort). We see that in either case, plaintiff's consent is employed to show that defendant owed plaintiff nothing, that, in effect, plaintiff's "freedom" in this context is the "freedom to lose."

Similarly, contracts involve consensual relationships entered into by two or more parties, with consent again being the underlying guarantor of an individual's freedom. Here each party bargains to receive something in return for his own promise. If there is a breach of the contract and one party does not receive the bargained-for performance, the courts will step in with a variety of remedies to protect that party's bargain, to preserve the "freedom" that he has obtained for himself via the consensual relationship. Again, this is the sense in which consent fosters individual freedom. Yet there is another side of the coin, one that is not nearly so often considered. This situation develops when a court finds a contract to be unconscionable (or illegal, against public policy, etc.), as when one of the parties does not get what he "should" from the bargain. In such a case that party's consent to the bargain will be set aside for the purpose of making him whole. There is a suggestion that it is the working of the "free market" that courts wish to support in their examination of such contracts.³³ Where this is absent in a contract, the courts will set it aside. Thus, even in contracts we find that it is not necessarily consent that is operating to promote individual freedom, but the operation of the free market. It is clear that such a free market does not exist for medical experimentation with humans. And its general existence in today's mixed economy is even a matter of some debate.

Thus the freedom of consent that we have been examining seems to be a strange form of freedom indeed, for it often appears to be the freedom to give up one's freedom.³⁴ We can buttress this with a reference to the workings of criminal law. In the area of search and seizure, the primary protection of an individual's freedom has little to do with consent at all: the requirement of a properly authorized warrant. In fact, consent to a search and seizure actually is tantamount to a *waiver* of legal protection, not a guarantee of it. Also, if a defendant's act is a crime, affecting the public interest, then the law will often refuse to accept the consent of the injured party as a defense.³⁵ We still make murder a crime, even when the victim is willing.³⁶ In addition, there are criminal statutes, such as those fixing the age of consent to sexual intercourse, which are clearly intended to implement a well-defined public policy—that of protecting a particular class of persons against their own lack of judgment, and thus against their own consent.³⁷

To varying degrees the preceding examples serve to focus our attention on the fact that there are some circumstances in which consent alone simply will not adequately safeguard the rights of an individual. Recognizing this fact, the state has frequently stepped in as a third party to override consent or to require it where the individual wishes it waived.³⁸ The court opinions are generally some form of rationalization (or rejection!) of government paternalism based on the needs of society to protect itself from a person's actions and also to protect that person himself from the consequences of his behavior.³⁹

Consent in the Experimentation Context

These conflicting interests are equally reflected in the medical experimentation context, where doubts about the capacity of men to give informed consent at all starkly present themselves. While the concept of informed consent has always been accepted as the basic principle for judging the propriety of research with human beings, the law "has neither defined sufficiently well the substance and ambit of informed consent in therapeutic settings nor determined clearly its functional relevance for human experimentation."⁴⁰ In a word, informed consent "lacks specific construction and remains an ill-defined concept."⁴¹

In spite of this fact, the basic functions of informed consent have generally been considered as: (1) serving society's desire to respect each individual's autonomy and his right to make choices concerning his own life;⁴² (2) providing the subject with information and encouraging him to participate in the process so as to increase its rationality; (3) protecting the experimental process itself by forcing the investigator to scrutinize his protective measures carefully, by reducing civil and criminal liability for non-negligent injury to subjects, and by reducing adverse public reaction to the experiment; and (4) increasing society's general awareness about human research.⁴³ Paul Freund has written:

It bears repeating that consent will not protect a badly designed or negligently conducted experiment . . . it serves to force the experimenter to think through and articulate his project in terms of design, risks, and objectives, and thus it has a valuable reflexive effect on the enterprise itself, like the practice of a judge in writing an opinion rendering judgment (sometimes it "won't write").⁴⁴

It would be my view, then, that consent alone is not enough to warrant an experimental procedure. As Freund indicates above, a bad experimental design

cannot be immunized simply by procuring subjects' consent. We have to look elsewhere to protect the subject adequately. By *requiring* consent, though, we may promote a better experimental design, which in turn will help to protect subjects and will increase the public's acceptance of experimentation. Thus, requiring consent is really more for the immediate benefit of the experimenter himself and society at large than for the protection of the subject.⁴⁵

We observe that if consent were to be *sufficient* to allow an experiment to go ahead, it would clearly have to be both informed and truly voluntary to protect the subject, since there would be no other safeguards for him. On the other hand, if consent were to be merely *relevant* data in the decision whether to allow an experiment to proceed, *i.e.*, only one factor among many to be considered, and a person decided to go along with it voluntarily, then perhaps there would be no need to insist that the consent be fully informed (since the other "considerations" or factors would be seen to protect the subject from harm: *e.g.*, initial hospital review committee screening on the quality of the experimental design, including the protections for the subjects) as well as voluntary. And if we do *require* consent for an experiment, we then must ask whether it must be both voluntary and informed. We may wish to require something here, but are both of these elements strictly necessary? We can only answer this question by defining the content of consent in terms of the *reasons* for requiring it. If the reasons are of the public relations or improving-experimental-design sort, there would appear to be no necessity for insisting on these twin requirements. If the reason is more one of acknowledging the freedom of a person to dispose of his own body, then perhaps the double requirements of informed and voluntary consent must be satisfied. We note in passing that the more additional requirements there are to be met before an experiment with a human subject can go on, the less necessary it is to build in strict consent requirements.⁴⁶

As I have noted, it appears that the strongest case for requiring informed *and* voluntary consent is where it is sufficient to allow an experiment to go ahead. An important question is whether voluntariness and the need for information are affected by the fact that an experiment is therapeutic rather than solely experimental. The traditional position appears to be that there should be a higher duty to inform and secure a voluntary consent with a nontherapeutic subject.⁴⁷ The physician/experimenter will not be allowed to withhold information from a subject that would normally qualify as an exception to the disclosure requirement in the doctor-patient context, because the policy permitting risks to be hidden from a patient when it is important for him not to worry can have no application in the field of research.

Yet there is impressive commentary the other way. For example, Professor Alexander Capron argues with some force that there is a *higher* need for information and voluntariness in the therapeutic situation because of the psychological posture of the patient grasping for a cure and because of the sheer power that a treating doctor possesses over a patient.⁴⁸ He recognizes that although there is some truth to the observation that all treatment is experimentation, there is still a great difference in the psychological contexts of a therapeutic and a nontherapeutic procedure. Thus, he would demand a higher standard for therapy, particularly when an element of honest experimentation is joined with the therapy.⁴⁹

Contrary to either of the previous two positions, one could say that it is irrelevant whether the procedure is primarily therapeutic or experimental. In order

to safeguard the subject's interests, then, we might wish to determine whether there is an immediate benefit to be gained from the experiment (whether to the subject, society, etc.), and perhaps set a higher standard where such a benefit is lacking. This discussion should serve notice that there is some serious disagreement as to the proper scope for the role of consent in the varying experimental contexts.

It may be helpful at this point to examine how the courts have treated the concept of informed consent. We should continue to bear in mind the many hats that consent is wearing: basic protection of subjects, promoting individual autonomy, enhancing rational decision-making, safeguarding the experimental process itself (for example, by removal of civil and criminal liability), and increasing society's awareness of medical experimentation.

THE CASE LAW

Background

In *Schloendorff v. Society of New York Hospital* Justice Cardozo stated the base from which the concept of informed consent has developed: "Every human being of adult years and sound mind has a right to determine what shall be done with his own body . . . except in cases of emergency where the patient is unconscious and where it is necessary to operate before consent can be obtained. . . ."⁵⁰ The case revealed the possibility of legal action against a physician for assault and battery where a person has not consented to the operation performed.⁵¹ Such a "touching" has been viewed as an intentional interference with the person—a battery.⁵² A physician's misrepresentation of the nature of the operation or the risk of undesirable consequences has been found to invalidate a patient's consent, leading to battery.⁵³ Also, where the physician knew the inevitable consequences that follow an operation and yet failed to disclose them, he has been held liable.⁵⁴ Even if the particular operation is beneficial or harmless, patients can still recover nominal or very limited damages.⁵⁵ Furthermore, no testimony as to the standard medical practice in the community is required in battery, for liability is not based on a standard of care but rather on an unlawful touching.

Negligence has developed as an alternative theory of recovery for patients, for in many circumstances in which a patient consented to a particular treatment and an undisclosed risk materialized, courts have been reluctant to find an intentional tort.⁵⁶ Rather, courts have more recently tended to hold that if a doctor in the course of treatment fails to utilize the degree of skill and care that would be exercised by reputable practitioners in the community under similar circumstances, and injury follows, then he will be held liable for damages for failure to adhere to the prescribed standard of care.⁵⁷ And this standard applies both to the performance of the operation itself and to the sufficiency of disclosure of risks and alternatives.⁵⁸

Whether a jurisdiction employs the battery or the negligence theory, it is clear the patient must be informed of the risks of the treatment and must give his consent to it.⁵⁹ Risks that are common knowledge need not be disclosed⁶⁰; disclosure of "material" risks is sufficient.⁶¹ And physicians will be held responsible for revealing only those material risks that are known to other comparable medical practitioners in the community.⁶² Yet there is substantial disagreement among jurisdictions as to what actually constitutes a "material" risk.

Most American jurisdictions adopt a community standard to determine the scope of disclosure for medical risks—those which are consistent with the practice of the local medical community.⁶³ What would make it difficult for plaintiffs to recover for injuries suffered according to this standard is the fact that expert medical testimony is required to establish a breach of local medical standards.⁶⁴ The often-mentioned “conspiracy of silence” within the medical profession may pose very large problems for patients/subjects trying to establish a physician’s failure to live up to the local standards.⁶⁵ Furthermore, such a rule clearly is based on the perceived primary duty of the physician “to do what is best” for his patient, the secondary duty being the one of disclosure.⁶⁶ Thus, “the patient’s right to select treatment is severely limited when it is based only on information deemed worthy of disclosure according to a medical community standard set by those under the obligation to inform.”⁶⁷ Such a rule, then, runs the risk of completely devouring one of the fundamental interests that informed consent is supposed to protect—that of self-determination and individual autonomy. Thus, courts *think* they are protecting the individual’s best interests when they pour meaning into a doctrine whose purpose they do not seem fully to understand.⁶⁸ I call attention to this problem, and suggest that recognition of it may go far in altering the legal formulations given to informed consent. Hopefully, such developments will bring the law more into line with the reality of the experimental process and the true functions that consent is able to serve.

Recent Formulations

Fortunately, there are some recent cases that do abolish the medical community standard and that turn to new tests for measuring the physician’s obligations of disclosure.⁶⁹ While the tests essentially adopt a “reasonable man” standard, the problem is that they apply it to different elements of the case, and there is need for more consistency here. We shall briefly consider the three cases that present these problems with the reasonable man standard: *Canterbury v. Spence*, *Cobbs v. Grant*, and *Wilkinson v. Vesey*.

In *Canterbury v. Spence*, plaintiff Canterbury had brought an action against defendant’s physician Spence and Washington Hospital Center for personal injuries allegedly sustained as a result of Spence’s negligence in operating, his negligence in failing to disclose a risk of serious disability inherent in the operation, and negligent postoperative care by the Hospital. At the close of plaintiff’s case, the trial judge directed verdicts for both the surgeon and the hospital. On appeal, the District of Columbia Court of Appeals reversed, holding that the evidence presented a jury issue as to the surgeon’s disclosure and his negligent conduct of the operation. As to the question of the materiality of information to be disclosed, the court adopted a reasonable man standard: “The scope of the standard is not subjective as to either physician or the patient; it remains objective with due regard for the patient’s informational needs and with suitable leeway for the physician’s situation.”⁷⁰ *I.e.*, the physician may have leeway to withhold certain collateral risks, either in emergency situations or where “risk-disclosure poses such a threat of detriment to the patient as to become unfeasible or contraindicated from a medical point of view.”⁷¹

Regarding the issue of causality, the court noted that a causal connection exists when, and only when, disclosure of significant risks incidental to treatment would

have resulted in a decision against the treatment. The objective standard adopted to determine this is what a prudent person in the patient's position would have decided if suitably informed of all perils bearing significance.⁷² While granting that the patient's testimony on this score would be relevant but not controlling, the court rejects the subjective causality standard, since the question whether the patient actually would have turned down the treatment if he had known the risks is purely hypothetical. "Viewed from the point at which he had to decide would the patient have decided differently had he known something he did not know?"⁷³ Such a test would place the physician in jeopardy of the patient's hindsight and bitterness or disillusionment with his treatment and its results. The court thus *rejects* a technique that would tie the factual conclusion on causation simply to an assessment of patient's credibility on the question of whether or not he would have foregone the treatment.

Cobbs v. Grant adopts a slightly different approach. The case involved a suit by Cobbs for negligent treatment of a duodenal ulcer that entailed surgery and the development of serious complications inherent in the surgery that had not been disclosed to plaintiff beforehand. Verdict was for Cobbs, and the surgeon appealed. The Supreme Court of California reversed, finding (1) that there was insufficient evidence to support the verdict on the theory of the surgeon's negligence during the operation, and (2) that, in view of the instructions to the jury, it was impossible to tell from the record whether the jury found the surgeon liable for his decision to operate, for negligently performing the operation, or for failing to obtain an informed consent. The court was quite clear in adopting an objective standard for the issue of causality, as did the court in *Canterbury*.⁷⁴ While the court here did reject the community standard rule as to disclosure as "overbroad" and "nebulous," it is unclear *what* standard was adopted for the question of materiality. It appears that the court focused most of its attention on causality, leaving materiality undefined but also implying a *subjective* test for it: "The scope of the physician's communications to the patient . . . must be measured by the patient's need, and that need is whatever information is material to the decision."⁷⁵

Wilkinson v. Vesey differs from the preceding two cases in that it adopts an *objective* materiality standard (as in *Canterbury*) but a *subjective* causality one. The case involved a malpractice action against radiologists by a patient who had suffered severe radiation burns. Plaintiff alleged three grounds for her action: (1) incorrect diagnosis of her ailment; (2) improper administration of the X-ray therapy; and (3) failure of defendants to obtain her informed consent. The trial court directed a verdict for defendants, and plaintiffs appealed; the Supreme Court of Rhode Island sustained the appeal. As to materiality, this court also rejected the community standard: ". . . the patient's right to make up his mind should not be delegated to a local medical group."⁷⁶ The jury was found to be able to decide if the doctor had disclosed enough information to enable the patient to make an intelligent choice. "Materiality may be said to be the significance a reasonable person, in what the physician knows or should know is his patient's position, would attach to the disclosed risk or risks in deciding whether or not to submit to surgery or treatment."⁷⁷

The Rhode Island Court also analyzed the causality issue, and concluded that plaintiff would have to prove that if she had been informed of the material risk,

then she would not have consented to the procedure and that she had been injured as a result of submitting to the procedure.⁷⁸ Thus, the focus is shifted from what a “reasonable man” would have done to what the *particular patient* would have done—a subjective causality test.

It has been argued that not only is the subjective standard the appropriate one to adopt in determining the causation issue, but also that it should be expanded from simply allowing a plaintiff to recover where he can prove he definitely would have refused the treatment or procedure to permitting recovery for consequential damages resulting from the concealment.⁷⁹ The basic argument is that such a position is consistent with a requirement of causation for tort liability, “while increasing the scope of protection consistently with the reasons for informed consent.”⁸⁰ The crucial point to be made here is that the argument cited above is only half correct while it masquerades as a full, complete answer to a complex problem. To permit a subjective standard to control on the issue of causation is to protect *only some* of the underlying policies for informed consent: the recognition and preservation of personal autonomy and the promotion of individual self-determination—in short, the choice or “freedom” to consent or to reject a proposed treatment or experimental procedure. We delude ourselves by believing that the subjective causality standard is the comprehensive “answer” to furthering *all* of the policies that consent serves. It does little to protect the experimental process itself, to ensure an adequate experimental design *before* consent is sought when such *ex post facto* attacks, based on a questionable hindsight, are permitted. It complicates the civil and criminal liability calculus for doctors rather than simplifying it. It does little to promote the scientific values of acquiring knowledge for the benefit of society as a whole, and may in fact discourage physicians/investigators from proceeding with innovative therapies and some clinical research, particularly when all possible risks are not and cannot be known beforehand (or else it would not even be a medical *experiment* at all). In short, such a standard takes a very restrictive view of utilitarianism by elevating one particular ethic to supremacy on the causation question, contrary to the Vaughan admonitions we discussed earlier.⁸¹ I am not saying that it is an “incorrect” approach; I am saying that its true merits can only be discerned by examining the policies that it actually serves and not the policies that someone *says* it serves.

In fact, it may be eminently reasonable to argue that the values promoted by the subjective causality standard are in fact those that we wish to see placed foremost in deciding the propriety of medical experimentations. One can argue that since informed consent is a two-pronged concept (disclosure by the doctor and voluntary consent by the subject/patient), holding the investigator to a reasonable man standard on materiality adequately protects his and society’s interests in disclosure. While valuing his expertise and providing for a limited exception to reasonable disclosure (emergency cases, therapeutic privilege—see n. 71), we still require that a doctor or investigator act not only as a professional, but as a reasonable man as well. The consent prong would seem to be adequately protected by the subjective causality standard if the primary policy is to foster individual decision-making. If this is only one of a number of competing policies to be served by consent, perhaps an objective standard would serve better.⁸²

Perhaps the most important point to be made in this regard is that there are competing policies served by consent. Neither the objective nor subjective causality

standard can possibly serve them all equally well and a frank recognition of that fact would lead to an analysis and general debate of the policies that society wishes to promote in particular therapeutic or clinical contexts. Such recognition would also lead to a functional, comprehensive definition of consent that would adequately serve the most important values for each type of medical experimentation procedure. At the present time, little such awareness, analysis, debate, and formulation of functional definitions seems to be taking place at a level of generalized public discourse. It would be worthwhile to look into ways in which such discussion can be generated.

COMPREHENSION AND INFORMED CONSENT

The Problem of Comprehension

Thus far, we have focused on “information” and “consent” as two separate activities, serving different needs, and with different requirements for effecting their underlying policies. The dichotomy is a bit misleading and too simplistic, and there is another element that merits our consideration: understanding, or comprehension. It can be argued that a person must be able to comprehend the information which has been conveyed to him before he can give a truly voluntary consent.⁸³ While the concepts of “information” and “consent” remain unsettled to a large degree, we have yet to see judicial commentary on and development of “comprehension.”⁸⁴ I stress its importance, if only because failures of comprehension may completely undercut the objectives of information and consent that the courts are so willing to assume effectively further the underlying policies. This, too, is an area of needed inquiry, for it goes right to the substantive question of whether consent can actually serve the interests of individual freedom, autonomy, and dignity that are generally assumed to be effectively protected by a stiff consent requirement. Such an inquiry directly calls into question the validity of the whole enterprise that seeks to protect subjects through a continued fleshing-out of the consent doctrine.

If we really desire to protect the rights and integrity of subjects in the experimentation process, then the informed consent doctrine must of necessity take account of the limitations on a subject's ability to make intelligent decisions. It is not sufficient to obtain a consent that is “informed” and adheres to the proper legal procedures but is not an understanding one. Comprehension by subjects simply cannot be assumed. Thus, we have to look at the “impediments to self-determination and informed consent inherent in the intellectual capacities, psychological forces, and social pressures operating in and on man.”⁸⁵ And even more specifically, it would seem necessary for us to inquire whether an awareness of these problems on the part of both investigators and subjects can overcome the failures of communication, understanding, and intelligent decision-making now plaguing the research process. Further, this is an inquiry that might usefully distinguish between therapeutic procedures and nontherapeutic medical experimentation, for it would seem that the closer one comes to a purely therapeutic context the greater are the barriers to full comprehension by the subject.⁸⁶ We should also emphasize here, again, that if informed consent is not needed just to protect autonomy but for other purposes (*e.g.*, self-scrutiny by the investigator, improve the experimental design, etc.) then it may not be necessary to have both an informed and a voluntary consent, and the questions as to comprehension would then not be nearly as important or relevant to the experimentation process.

But if protection of freedom, autonomy, and dignity is our goal, then an understanding of comprehension is crucial to the analysis.

A Symbolic Commitment

I might add a brief note here. If in fact it was determined that, realistically, a truly informed consent with maximum comprehension could never be achieved, then we still might require informed consent to medical experimentation. The reason would be to maintain a societal, *symbolic* commitment to the values of freedom and autonomy in human experimentation. It would be a recognition that there is an irreducible “something” that constitutes man, that separates him from other living creatures that is not to be violated or transcended, for fear of obliterating that very essence of man that makes life worth living: his own dignity as a man. Thus, taking utilitarianism in its broadest of possible meanings, one can argue that this symbolic but very real commitment in medical experimentation to what are perceived as fundamental societal values, though of perhaps no utility in the human experimentation process itself, finds its utility in the protections it affords other aspects of life.

It is also true, however, that there may be losses resulting from the symbolic gains and commitments to which I have just referred, particularly if the exclusive gain is in fact a symbolic one. One rather serious effect is that if informed consent *only* serves as a symbolic commitment to our values of freedom, autonomy, and dignity, and if we *believe* that it is the central protective device for subjects in medical experimentation, then this may lead to complacency in our efforts to discover other more effective means for protecting subjects and for actually promoting the important values of freedom, autonomy, and dignity. Unfortunately, this is the situation that has largely developed with regard to medical experimentation today.

Limitations to Comprehension

If we are aware of the weaknesses of the informed consent doctrine, then perhaps knowledge of these limitations can help us find ways of dealing with the limitations. Among these limitations is the very basic controversy over the degree to which man actually possesses free will.⁸⁷ Whether he does or does not—and whether it is ever really possible to find out—the doctrine of informed consent *assumes* the existence of a free will and that a subject will in fact use the information provided to him in order to decide whether or not to consent to a medical procedure. Experience with renal transplants suggests that informed consent simply may be a myth:

. . . all donors and potential donors interviewed by us reported a decision-making process that was immediate and “irrational” and could not meet the requirements adopted by the American Medical Association to be accepted as an “informed consent.”⁸⁸

If we were to assume that people actually used the information that they were given, then we would like to know how likely it would be for subjects to have the necessary information. I noted earlier some of the problems related to materiality of information and the current disclosure requirements for physicians and medical investigators.⁸⁹ It is of course impossible to give all information anyway, so we wish to maximize the impact of that actually transmitted. Consent can be sought and given orally, in writing, or both. To maximize understanding, both should probably

be required, unless of course the patient or subject is uncomprehending.⁹⁰ For example, recent DHEW guidelines applicable to all research grants and contracts involving the use of human subjects require only a written consent, but do make clear that some oral explanation will usually be in order.⁹¹ The written consent at least is more common in human research, for it is thought to provide subjects with better information and researchers with better legal protection.

A Procedural Innovation

One of the more interesting recommendations for obtaining informed consent has been proposed by Robert Miller and Henry Willner. They propose the use of a two-part consent form, which includes a questionnaire to check how well subjects understand the information given in the written form itself.⁹² The proposal is aimed primarily at eliminating barriers to comprehension caused by failures of communication and understanding, whether through basic language problems, cultural differences between the investigator and the subject, mis-speaking and mis-hearing, etc.⁹³

The first part of the form includes the written consent required by DHEW in 45 C.F.R. 46 and three additional elements: (1) an instruction that the person is free to refuse to participate; (2) an explanation that such a refusal will not prejudice either future treatment or future relations with the institution; and (3) an explanation of why the person was selected and what the purpose of the experiment is.⁹⁴ The second part would be the questionnaire, providing questions as to the benefits of the experiment, departures from ordinary medical practice, inconveniences, risks, purposes, and the subject's rights.⁹⁵

If it is determined that the subject's answers to the questionnaire reveal a "proper" understanding of the procedure, then he could be asked to participate. If he consents, he can be given a copy of the consent form to keep. This does two things: (1) It permits him to subject his involvement in the experiment to continuing informed review, either by rereading the form, or by discussing it with fellow patients or subjects; and (2) it will help the subject detect differences between his actual experience in the experiment and what he expected. Discrepancies can be brought to the investigator's attention.⁹⁶

Should the subject's answers be deemed unacceptable, there are several alternatives: (1) have the subject reread the description of the experiment and answer the questionnaire a second time; (2) provide an oral explanation of the procedure and then give the subject another questionnaire; and (3) after repeated failures, disqualify the subject if the experiment is nontherapeutic or obtain the consent of the person's legal guardian or representative if the procedure is a therapeutic one. It should be evident that if a subject continually fails to give satisfactory answers as to the experiment, then either or both of two problems may be present: (1) the explanation of the experiment is poor (faulty experimental design); (2) the subject is not competent to make the informed consent decision for himself.⁹⁷

While there are still some bugs in such a proposal, the basic idea strikes me as sound. We may never get to a point where subjects possess perfect understanding of experiments, but perhaps we can do some concrete things to minimize problems of understanding and confusion. To the extent that this objective can be achieved, the preceding proposal is worthy of serious further consideration. But whether it can ever actually go to the root problem of subjects actually protecting themselves

via informed consent is another matter. Certainly such a procedure gives the experimenter good feedback as to the clarity of his experimental design (though not necessarily its quality) and does evidence a human concern to involve the subject more personally in the experimentation process, sufficient reasons for warranting the extra time, money, and effort to implement it.

PROBLEMS WITH SUBJECT GROUPS

Experimentation with Uncomprehending Subjects

Up to this point we have been evaluating how well people seem to utilize the information they receive in deciding whether or not to consent to an experiment. There seem to be many obstacles to effective use of the available data. A further complicating factor is that differences between certain identifiable subject groups may dramatically affect the capacity of the people within those groups to give an informed consent. At a minimum, we can identify true volunteers, those requested by an investigator to participate, patients in therapeutic and patients in nontherapeutic situations, prisoners,⁹⁸ children,⁹⁹ old people and the dying,¹⁰⁰ and mental incompetents.¹⁰¹ Although a detailed analysis of the special problems faced by each one of these groups in giving informed consent is obviously beyond the scope of this paper, I would like to examine briefly the "uncomprehending subjects" category, which includes both children and mental incompetents, to illustrate some of the acute dilemmas that such subjects present for medical experimentation.

As a general proposition, we may state the obvious: The further away from true volunteers we move, the more we increase the problems of effective utilization of information so as to produce the best possible informed consent. When we reach the category of the uncomprehending, two basic questions arise immediately: (1) When, if ever, should subjects be used for research without their own consent?; (2) What persons or institutions should be authorized to formulate, administer, and review rules about the participation of nonconsenting subjects?¹⁰² These questions arise because we do need children as subjects, especially for investigations into the special diseases of children and for general knowledge regarding the early stages of life and its processes. And there is an acute problem of lack of a protective structure for children and incompetents aside from consent, since the further the locus of the decision-making as to consent is from the child subject, for example, the less certain we can be that the consent decision actually coincides with the child's value preferences and desires. The more uncomprehending the subject, the greater the need to place the decision outside that subject and the more the policies of freedom, autonomy, and dignity that the consent rule is supposed to promote in the first place are undercut.

In using children as subjects of medical experimentation, is the nature of the threat of harm greater than in a comparable experiment that employs adults? One harm that may be difficult to evaluate is that we may either prevent or retard the child's natural development with a psychological harm that may affect the child much more than it would an adult, since the child possesses both an unformed body and mind. Experimenting with a child may deprive him of the chance that other people have to arrive at the stage of adulthood comparatively unmolested. The argument against experimentation would be that society sees childhood as something of a grace period, as a time to shield children from harm so that they will

be able to develop to a point where they can actually exercise their own freedom and autonomy. This is the essence of paternalism and probably in fact reflects a fundamentally shared societal value that may warrant extra protection from medical experimentation.

Turning to mental incompetents for a moment, there may be reasons for treating them differently than children (though both groups are uncomprehending). Our assumption as to experimenting on children was that it could lead to psychological harm and retard their development. With mental incompetents not capable of being educated any further, this assumption could well be irrelevant. We would conclude that it is probable that less harm is done in experimenting on mental incompetents. And in a gross sort of utilitarian way, it can be argued that such incompetents do not and cannot contribute to society.

Yet such arguments may be balanced by emphasizing the symbolic commitment to the values of freedom, autonomy, and dignity that our society maintains through the informed consent requirement, whether it is the person himself or his legal guardian or representative who ultimately decides whether or not to give consent. This is the recognition of the idea that there is a limit to the extent of man's violability. In fact, the symbolic commitment argument may carry more weight with children and mental incompetents, simply because these potential subjects do not possess the capacity to prevent their own violation *at all*, and hence cannot even fulfill the minimal requirements necessary to make consent a viable protection for their interests.¹⁰³ We may be particularly sensitive to the possible "brutalization of society" through experimenting with children and incompetents. Also, children are the "future" and society may be wary of mortgaging that too soon. These factors do not necessarily militate against such experiments, but they do suggest that our calculus of decision should recognize these considerations and weigh them as additional, relevant information.

Fixed Rules and Benefits

If we focus on the specific harm involved in experimentation on these uncomprehending groups, there seem to be three general approaches: (1) treat the uncomprehending just like all other experimental subjects; (2) set up special rules for the children and mental incompetents; and (3) take each case by itself, on its facts, and take into account as one additional factor the status of youth or incompetence. There is a tendency to treat the uncomprehending subjects with special rules.¹⁰⁴ The rules, however, can seem too rigid in certain circumstances, and so exceptions tend to be made. But the more cases we decide according to "rules with exceptions" the closer we seem to get to the case-by-case approach.

Problems arise in attempting to apply set rules to experimentation with uncomprehending subjects. We recall that the Nuremberg Code stated that people involved in experiments should possess the legal capacity to consent.¹⁰⁵ A strict reading of that Code would seem to rule out all uncomprehending subjects. Such a hard line was rejected in the Helsinki Declaration which indicated that minors could be used if (1) mentally competent adults were unsuitable for the investigation, and (2) the consent be given in writing by the legally authorized representative of the subject "under circumstances in which an informed and prudent adult could reasonably be expected to volunteer himself or his child as a subject."¹⁰⁶ But Chief Justice Burger has gone so far as to state that "no adult has the legal power to

consent to an experiment on an infant unless the treatment is for the benefit of the infant.”¹⁰⁷ This seems to be the prevailing American legal doctrine, and it has led to some strange formulations of the concept of “benefit.”

Traditionally, therapeutic operations on young children have always required the consent of the parent.¹⁰⁸ Minors approaching the age of maturity have been held to be capable of giving their own consent.¹⁰⁹ But emergency situations will permit a waiver of any consent requirements so that life may be saved, even when the parents cannot be reached in time.¹¹⁰ Further, where the parent unreasonably refuses consent a court may, as in other cases where it is necessary to act for the welfare of the child, remove him from the custody of the parent, and appoint a custodian, who may then consent to the operation.¹¹¹ While the courts speak in terms of an implied consent in the latter two situations, we might more properly view it as permitting the physician to make the reasonable assumption that if the patient had been competent and had understood the situation, he would have consented, and so the physician is entitled to proceed.¹¹² While these doctrines seem well-settled in the therapeutic context, they may be open to question the closer we move toward clinical research.

A most interesting illustration in this regard arose in 1957 when the Supreme Judicial Court of Massachusetts issued three highly significant opinions in declaratory judgment proceedings in a developing area of medical science: the homotransplantation (from one human being to another) of functioning tissue (kidneys).¹¹³ The first successful kidney transplants had taken place in identical adult twins in 1954 in Peter Bent Brigham Hospital in Boston.¹¹⁴ By 1956 there were requests for similar procedures on minor identical twins, where one of the twins was suffering from chronic renal disease which would soon have been fatal. The question was whether or not the consent of the parents (actually a request) was sufficient to warrant the hospital to go ahead. Unsure of its legal position, the hospital sought legal guidance.

As we have seen, in most cases with minors parental consent on treatment was controlling, but this applied only when the treatment was to be for the benefit of the child.¹¹⁵ Here, parental consent to the operation on the kidney recipient was proper. However, whether parents could consent for the donor was another question. Half of the “treatment” appears to be therapeutic and half experimental, since taking one kidney away from a healthy donor could leave him open to some potentially serious future risks. In *Masden v. Harrison* (two nineteen-year-olds) the judge heard testimony from the consenting parent and the donor twin, who seemed fully informed and willing to give his consent.¹¹⁶ Psychiatric testimony was also taken, the judge finding that if the operation were not performed and if the sick twin were to die then this would produce a “grave emotional impact” on the donor twin.¹¹⁷ Thus, the judge found benefits to both twins and allowed the operation. Psychiatric testimony was produced in the other two Massachusetts cases as well, with the judge finding the benefits to both donor and donee to be sufficient enough to warrant the transplant.

As Curran has indicated, “. . . the benefit found by the court with the aid of psychiatric evidence is more the prevention of possible detriment than it is the conferring of a positive gain.”¹¹⁸ The cases raise immediate problems regarding the “benefits to the donor.” Note that we are speaking of operations on a child that

have no real direct benefit to himself, but may be very beneficial for others, whether they be his brothers or sisters, parents, friends, etc. In spite of a clear rule allowing no experimentation on minors unless for their own benefit,¹¹⁹ these three cases reveal how easy it is for a court to find “benefits” to a donor if it really wishes to do so.

Thus, the rule against such experimentation does not really protect potential subjects at all, and it is illusory to think that it can. While torturing themselves to fit the situation into the rule, courts are really deciding such cases on an individual basis, after considering all the relevant circumstances. But few other subject safeguards have yet been developed to make sure that a child donor actually has any substantive protection beyond that supplied by the deciding judge. It seems to me quite short-sighted to insist on the benefit rule if it can be so easily met with all sorts of “trumped-up” benefits. In line with my general thinking, it may be that we do not want hard and fast rules applicable to experimentation on children. But we should consider childhood itself as an important factor in making the decision (perhaps apply the “sliding-scale” as to a child’s comprehension), as well as any unusual benefits or risks to others and to society as well as to the donor child.

Curran and Beecher propose a scheme for child donors in experimental cases such as the kidney transplants.¹²⁰ For organ donations, they suggest that the donor be fourteen years of age or older, intelligent, and mature enough to give informed consent, and that his parents also give consent. Also, they indicate that donations could be restricted to relatives or close friends.¹²¹ The suggestions on lowering the donor age and emphasizing his comprehension may be good ones. But trappings of the old inadequate protections exist in setting a definite age limit and restricting the donee class.¹²² For nontherapeutic experiments, they require that children under fourteen years may participate where there are no direct benefits to themselves, where the studies are sound, promise important new knowledge for society, and there is no discernible risk. If the child is over fourteen, his informed consent would be sufficient, and parents would only be required to consent in cases where there are discernible risks. Insofar as this approach looks to the quality of the experimental design, the gains to be achieved, and risks to the donor it begins to focus on the real protective devices for donors. Otherwise, the formulations of Curran and Beecher reflect many of the traditional misconceptions as to the utility of consent as well as the difficulty of abandoning it for more substantive subject protections.

Recent Cases

Two other transplantation cases deserve mention before closing. In very few states is there clear precedent which would indicate that a parent or guardian has the power to consent for a child to a surgical procedure which is for the therapeutic benefit of someone other than the child himself. In the two leading recent cases dealing with this problem,¹²³ courts have found that they have equity power to authorize parents or guardians to consent to the procedure. *Strunk v. Strunk* involved two brothers, Tommy, aged twenty-eight with chronic kidney disease, and Jerry, an incompetent of twenty-seven years of age whose mental age was estimated to be about six years. The desired operation was a kidney transplant from the younger incompetent to his older brother.¹²⁴ Jerry’s mother filed an equity petition seeking authority to give consent to the surgical procedure for him. The Kentucky court relied on the “doctrine of substituted judgment” to establish its equity power to authorize the parent’s consent:

The right to act for the incompetent in all cases has become recognized in this country as the doctrine of substituted judgment and is broad enough not only to cover property but also to cover all matters touching on the well-being of the ward.¹²⁵

The holding here was therefore based on a finding, after taking psychiatric testimony, that there would be an extremely traumatic effect on the incompetent if his only brother died.¹²⁶ The “benefit” to Jerry from the transplant was protecting him from the materialization of the trauma.¹²⁷ Again we see a court that hung its holding on the “benefit” rule but actually decided the case—fortunately—on a comprehensive look at all the facts of the case. It is illusory to believe that a benefit rule can actually produce the best result in every concrete case.¹²⁸

Hart v. Brown dealt with two seven-year-old twin girls, one suffering from kidney disease, the other perfectly healthy.¹²⁹ The parents brought an action for a declaratory judgment as to the authority to consent to a kidney transplant from the healthy twin to the ill one. The court here, too, relied on the doctrine of “substituted judgment” to approve the operation, but qualified its opinion by requiring a “close, independent and objective investigation of their [the parents’] motivation and reasoning.”¹³⁰ Further, the court held that the need for the operation would have to be urgent, the probabilities of success most favorable, and the duty clear.¹³¹ Again, there was reliance on psychiatric testimony showing that the donor twin would have a better family life if her sister were enabled to live.

We see a favorable development in this case of a court of equity taking account of the facts of this *particular* case to do both justice and common sense. In objecting to an overly structured, formalized definition of consent applicable in different ways to different groups of subjects for medical experimentation, I have been arguing for a broad-based utilitarianism that will consider all the circumstances of a case to be relevant to the consent decision so as to maximize the protection of subjects through a well-considered application of common sense in a particular context. It seems to me that consent, while perhaps a relevant factor in determining whether to go ahead with an experiment, may not always be dispositive. It may be, if our primary concern is to promote human dignity instead of health, and if it is possible for a consent requirement truly to reflect our society’s esteem for the status of being human. The fundamental issue, however, must be that

... the manner in which experimentation is conducted may affect the trust among members of the community that society will protect the dignity of an individual irrespective of that individual’s ability to assert and enforce a claim to such protection.¹³²

It might, therefore, not be wise to dispense completely with the consent requirement in medical experimentation, for abandoning it may weaken the mutual trust which holds the members of a community together, because they could no longer be sure that they will be protected when they are unable to protect themselves.¹³³ If such protection is a major goal, then public awareness of the substantive weaknesses of the doctrine of informed consent should prompt us all—lawyers and doctors particularly—to begin the diligent search for effective alternative safeguards.

CONCLUSION

While this paper is by no means exhaustive, I do believe it reveals that we have been laboring under some serious delusions concerning the doctrine of informed consent. In short, we have tried to make the doctrine bear a load that it is simply incapable of handling. We assume that informed consent is the central protective device for subjects in medical experimentation, yet we find that there are such great barriers to both the function of informing and consenting that true informed consent perhaps cannot be achieved. And we never even stop to examine whether the subject has comprehended the data on which he is to base his decision. We have made consent an absolute value when we should be devising mechanisms to mediate between legitimate, conflicting ethical claims and values. And we have left the toughest ethical choices to the investigators, rather than making them the basis for serious public discussion, reflection, and clarification.

The end result is that patients/subjects are often lost in the shuffle. Aside from consent we have developed little in the way of substantive protections for subjects. Consent cannot guarantee either a good or an ethical experimental design, nor can it foster an equitable selection mechanism to obtain the subjects needed for important medical and scientific research. It is time that we stop deluding ourselves that we have found one answer to controlling the development of certain biomedical technologies, because such delusions invite complacency and a self-satisfied posture that can only be an invitation to disaster in the long run. Our need, then, is to continually question and challenge our operative assumptions, to seek new and better ways to cope with old problems. This is a matter of will, of the human spirit. It is not the technology that directly threatens man so much as it is his irrationalities, his vanities, and his pride.

One could conclude on a pessimistic note by suggesting that attempts to institutionalize the making of judgments between the individual and society in the context of medical experimentation are doomed to failure, due to the nature of severely conflicting values and goals of all the participants in the experimentation process: the investigators, subjects, the State, and certainly the professions. As professionals it is our duty to approach these conflicts in a rational manner. We can start by rethinking the informed consent doctrine in terms of its purposes and what it can realistically help us to achieve. These may only be the symbolic values that I have spoken of in this paper. If so, then we must search elsewhere to develop a rational control mechanism for medical experimentation that adequately balances, preserves, and promotes the plurality of interests and values that is the very strength of our culture.

FOOTNOTES

¹Tribe, *Channeling Technology Through Law* i-ii (1973).

²Katz, *Experimentation with Human Beings* 1 (1972).

³Freund, *Experimentation with Human Subjects* xii (1970). See also *Slater v. Baker and Stapleton*, C.B. 95 Eng. Rep. 860 (1767).

⁴Freund, *op. cit.* supra n. 3 at xii.

⁵Mazzeo, *The Design of Life* xiii (1967).

⁶Katz, *op. cit.* supra n. 2 at 112.

⁷My focus is the more limited area of medical experimentation rather than scientific experimentation conceived in its broadest sense, although many of the principles derived herein may be equally applicable in any experimental context. I will discuss standard medical therapy, innovative or experimental therapy, and nontherapeutic (clinical) research.

⁸Note, "Informed Consent and Human Experimentation," 5 *N. Car. Cent. L.J.* 254 (1974).

⁹Katz, *op. cit.* supra n. 2 at 1.

¹⁰Calabresi, "Reflections on Medical Experimentation in Humans," in *Experimentation with Human Subjects* 178 (P. Freund, ed., 1970).

¹¹*Id.* at 184.

¹²Freund, *op. cit.* supra n. 3 at xvii.

¹³I am assuming that the medical experimentation process can be rationally controlled, whether it be through the law alone or law reinforced by other protective devices.

¹⁴Jonas, "Philosophical Reflections on Human Experimentation," in *Experimentation with Human Subjects* 1, 6 (P. Freund, ed., 1970).

¹⁵Freund, "Legal Frameworks for Human Experimentation," in *Experimentation with Human Subjects* 105 (P. Freund, ed., 1970).

¹⁶Katz, *op. cit.* supra n. 2 at 5.

¹⁷*Id.* at 105 citing Vaughan, "Governmental Intervention in Social Research—Political and Ethical Dimensions in the Wichita Jury Recordings," in *Ethics, Politics and Social Research* 50, 60-75 (Gideon Sjöberg, ed., 1967).

¹⁸Writing in a different context (the relationship between ideology and politics in contemporary society) but focusing on a similar problem, Professor Edward Shils said:

. . . civil politics require an understanding of the complexity of virtue, that no virtue stands alone, that every virtuous act costs something in terms of other virtuous acts, that virtues are intertwined with evils, and that no theoretical system of a hierarchy of virtues is ever realizable in practice. It has been a major fault of ideological politics that they have made the mistake of thinking that a coherent, systematic doctrine could guide conduct unfailingly along a straight line which made no compromise with evil. Ideological politics believed that the more strictly one adhered to a virtue, the more intensely one was attached to it, and the more completely one fulfilled it, the better would be one's actions.

Shils, "Ideological Politics Versus Civil Politics," in *Ideology, Politics and Political Theory* 216, 238 (R. Cox, ed., 1969).

¹⁹Katz, *op. cit.* supra n. 2 at 282.

²⁰*Id.* at 283.

²¹The articles were drafted by a committee of the A.M.A. and set forth 10 basic criteria for nontherapeutic research. They included: (1) a voluntary consent by each subject; (2) human subjects were to be used only when fruitful results for the good of society unprocureable by

other means may be promoted; (3) the experiment must be based on prior animal experimentation and on knowledge of the natural history of the problem; (4) unnecessary physical and mental suffering must be avoided; (5) there must be no likelihood of death or disabling injury; (6) the risk must be set off against and cannot be greater than the humanitarian importance of the project; (7) proper preparation and facilities must be provided; (8) scientifically qualified investigators must be used; (9) the subject of the investigation must be free to withdraw at any time; and (10) there must be an assurance that the investigators will terminate the project if at any time it seems to be getting out of hand.

The actual text of the articles can be found reprinted in Beecher, "Experimentation in Man," 169 *J.A.M.A.* 461, 472-74 (1959).

²²See American Medical Association, "Principles of Medical Ethics," 132 *J.A.M.A.* 1090 (1946); American Psychological Association, "Ethical Standards of Psychologists," 14 *Am. Psychologist* 279 (1959); World Medical Association, "Code of Ethics of the World Medical Association Declaration of Helsinki," 2 *Brit. Med. J.* 177 (1964); *Medical Research Council*, "Responsibility in Investigations on Human Subjects," 2 *Brit. Med. J.* 178 (1964); "American Medical Association Guidelines for Clinical Investigation," 198 *J.A.M.A.*, Sept. 12, 1966; 21 C.F.R. §130.37 (1974) (Food and Drug Administration regulations on consent).

See also Stason, "The Role of Law in Medical Progress," 32 *Law and Contemporary Problems* 563, 587-91 (1967); Note, "Informed Consent and Human Experimentation," *op. cit.* supra n. 8 at 254-57.

²³Also printed in 271 *New Eng. J. Med.* 473 (1964).

²⁴*E.g.*, the doctor himself must explain the nature, purpose, and risk of the experiment, the consent must be in writing, the subject must be in "such a mental, physical, and legal state as to exercise fully his power of choice," and the subject may withdraw at any time. None of these are required in the therapeutic experiment. See "Declaration of Helsinki," *op. cit.* supra n. 23 at 473.

²⁵See, Katz, *op. cit.* supra n. 2 at 318 citing McDermott, "Opening Comments on the Changing Mores of Biomedical Research," 67 *Annals of Internal Medicine*, supplement 7: 39-42 (1967).

In an interesting article, Henry K. Beecher is also quite critical of the widespread "myth" that codes (all of which emphasize, above all, consent) will provide subjects some kind of security. He is concerned that rigid adherence to a code can lead to a dangerous trap: no two situations are alike, and it is impossible to spell out all contingencies in codes. He then goes on to show how difficult it is to obtain consent anyway, another problem that the codes overlook and to which we shall return. See Beecher, "Consent in Clinical Experimentation: Myth and Reality," 195 *J.A.M.A.* 34 (1966).

²⁶Beecher, "Ethics and Clinical Research," 274 *New Eng. J. Med.* 1354, 1360 (1966).

²⁷Katz suggests that subjects are not best protected by a doctor's ethical training because ethics are not systematically taught. He suggests ways of changing this, his belief being that:

Education of doctors, more than codes and procedures, will teach us not to be led astray, though the latter will then find an important place to nourish conscience otherwise prone to compromise and corruption.

Katz, "The Education of the Physician-Investigator," in *Experimentation with Human Subjects* 293, 309 (P. Freund, ed., 1970).

²⁸*Id.* at 298.

²⁹Katz, *op. cit.* supra n. 2 at 521.

³⁰See Prosser, *Law of Torts* 103-105 (4th ed., 1971).

³¹Katz, *op. cit.* supra n. 2 at 521.

³²Prosser, *op. cit.* supra n. 31 at 101. See also Bohlen, "Contributory Negligence," 21 *Harv. L. Rev.* 233 (1908); Bohlen, "Consent as Affecting Civil Liability for Breaches of the Peace," 24 *Col. L. Rev.* 819 (1924).

³³See Uniform Commercial Code §2-302, Comment 1.

³⁴See generally Tribe, *op. cit.* supra n. 1 at 367-437; Katz, *op. cit.* supra n. 2 at 540-69.

³⁵Prosser, *op. cit.* supra n. 30 at 107.

³⁶Tribe, *op. cit.* supra n. 1 at 428. As with n. 35, the giving of consent does not protect the party who acts on reliance of its validity as insulation from legal liability.

³⁷Prosser, *op. cit.* supra n. 30 at 107. Note that where a defendant can show plaintiff's consent to intercourse in a prosecution for rape (or at least raise the issue for the jury's consideration), plaintiff is found to have waived legal protection from defendant's actions.

³⁸See especially the crash-helmet cases in Tribe, *op. cit.* supra n. 1 at 377-82.

³⁹Tribe describes four general explanations for societal intervention to prevent persons from doing certain things to themselves (or to force them to do certain things for themselves). It seems to me that the strongest argument for paternalism is his fourth (that there may be certain "rights" so basic to society as a whole that every person should be guaranteed their enjoyment "notwithstanding any supposed willingness to trade them, in the face of a technological option, for other valued experiences or objects." Tribe, *op. cit.* supra n. 1 at 428-35), although it does presume a societal consensus as to the nature of these "rights" that would allow them to be identified, articulated, and protected by law. I take it that the Tribe analysis is to (1) raise the question as to the existence of such "*fundamental* fundamental rights," and (2) initiate the debate as to their substance.

⁴⁰Katz, *op. cit.* supra n. 2 at 523.

⁴¹*Id.*

⁴²Note that requiring consent is an attempt to treat people as means and not ends. The phrasing here is beguiling, for in all experimentation, whether it be therapeutic or clinical, people are the *means* by which medical techniques are applied, refined, perfected, etc.

⁴³Katz, *op. cit.* supra n. 2 at 540-608.

⁴⁴Freund, *op. cit.* supra n. 3 at xvi-xvii.

⁴⁵Note that requiring the consent of a subject before an experiment can proceed does affect the freedom of the experimenter himself.

⁴⁶The special consent rules that exist for minors, prisoners, mental incompetents, the dying, etc. seem to be based on the assumption that consent itself is sufficient to warrant an experiment or innovative therapeutic procedure. Hence, we see in the literature extraordinarily tortured attempts to find that consent in these particular cases is both informed and voluntary. I believe this quest to be both futile and self-defeating, for I do not grant that consent alone should be *sufficient* to warrant a procedure. Rather, my suggestion would be that by adopting a different assumption as to the appropriate relationship of consent to medical experimentation our consent requirement would be different—*i.e.*, if there were other safeguards.

⁴⁷*Halushka v. University of Saskatchewan*, 52 W.W.R. 608 (Sask. 1965).

⁴⁸Capron, "The Law of Genetic Therapy," in *The New Genetics and the Future of Man* 133, 150-51 (M. Hamilton, ed., 1972).

⁴⁹This was the standard put forth in *Hyman v. Jewish Chronic Disease Hospital*, 42 Misc. 2d 427, 248 N.Y.S. 2d 245 (Sup. Ct. 1964), rev'd per curiam, 21 App. Div. 2d 495, 251 N.Y.S. 2d 818, rev'd, 15 N.Y. 2d 317, 258 N.Y.S. 2d 397, 206 N.E. 2d 338 (1965). The experiment involved the injection of cancer cells into chronically ill patients to measure their rate of rejection of the cells. The experiment had nothing to do with the patients' treatment, and they were not told of the real purpose of the experiment or that live cancer cells were being used. Consent was effectively "manipulated" out of the patients. The New York State Board of Regents took stern disciplinary measures against the doctors involved, emphasizing that in the nontherapeutic context doctors have no right to withhold information from patients that would be relevant to their consent decision.

- ⁵⁰211 N.Y. 125, 129, 105 N.E. 92, 93 (1914). See also 2 F. Harper and F. James, *The Law of Torts* §17.1 n. 15 (Supp. 1968).
- ⁵¹See, e.g., *Pratt v. Davis*, 118 Ill. App. 161, 166, aff'd, 224 Ill. 300, 79 N.E. 562 (1906); *Skitter v. Rochelle*, 2 Ariz. App. 358, 409 P. 2d 74, 82 (1965), modified on other grounds, 2 Ariz. App. 607, 411 P. 2d 45 (1966).
- ⁵²The intent need not be malicious. "Rather it is an intent to bring about a result which will invade the interests of another in a way that the law will not sanction." Prosser, *op. cit.* supra n. 30 at 31. See *Canterbury v. Spence*, 150 U.S. App. D.C. 263, 274, 464 F. 2d 772, 783, cert. denied, 409 U.S. 1064 (1972); *Berkey v. Anderson*, 1 Cal. App. 3d 790, 803, 82 Cal. Rptr. 67, 76-77 (1969); *Wilkinson v. Vesey*, 110 R.I. 606, 621, 295 A. 2d 676, 686 (1972).
- ⁵³*Paulsen v. Gunderson*, 218 Wis. 578, 260 N.W. 448 (1935).
- ⁵⁴*Bang v. Charles T. Miller Hosp.*, 251 Minn. 427, 88 N.W. 2d 186 (1958) (sterilization).
- ⁵⁵*Lacey v. Laird*, 166 Ohio Rep. 12, 139 N.E. 2d 25 (1956); *Keister v. O'Neil*, 50 Cal. App. 2d 428, 138 P. 2d 723 (1943).
- ⁵⁶See, e.g., *Cobbs v. Grant*, 8 Cal. 3d 229, 240-41, 502 P. 2d 1, 8, 104 Cal. Rptr. 505, 512 (1972).
- ⁵⁷Stason, *op. cit.* supra n. 22 at 581.
- ⁵⁸Note, "Informed Consent and the Dying Patient," 83 *Yale L. J.* 1632, 1636 (1974).
- ⁵⁹See Waltz and Scheuneman, "Informed Consent to Therapy," 64 *Nw. U. L. Rev.* 628 (1970).
- ⁶⁰*Wilkinson v. Vesey*, 110 R.I. 606, 629, 295 A. 2d 679, 689 (1972).
- ⁶¹*Getchell v. Mansfield*, 260 Ore. 174, 489 P. 2d 953 (1971); *ZeBarth v. Swedish Hosp. Med. Center*, 81 Wash. 2d 12, 25, 499 P. 2d 1, 9-10 (1972).
- ⁶²See *Riedinger v. Colburn*, 361 F. Supp. 1073, 1076-77 (D. Idaho 1973) (orthopedic surgeon testified to no personal knowledge of the risk that materialized and produced studies indicating it was "virtually unknown").
- ⁶³Presumably, a "specialist" would be held to a higher standard, due to the unique nature of his skills and knowledge. If an increasing number of people rely on specialists for treatment and if there is a trend within the medical profession toward specialty practice, then what does this say about the problems that courts will have determining just what the "community standard" is? And what guidance can the community standard give to both practitioners and patients, given this development? See Comment, "Informed Consent in Medical Malpractice," 55 *Calif. L. Rev.* 1396 (1967); Comment, "Valid Consent to Medical Treatment: Need the Patient Know?" 4 *Duquesne L. Rev.* 450 (1966).
- ⁶⁴*Grosjean v. Spencer*, 258 Iowa 685, 694, 140 N.W. 2d 139, 145 (1966); *Marchlewicz v. Stanton*, 213 N.W. 2d 317, 319 (Mich. App. 1973).
- ⁶⁵See *Huffman v. Lindquist*, 37 Cal. 2d 465, 484, 234 P. 2d 34, 46 (1951) (dissenting opinion); Comment, "Informed Consent in Medical Malpractice," 55 *Calif. L. Rev.* 1396 (1967).
- ⁶⁶*DiFilippo v. Preston*, 53 Del. 539, 550, 173 A. 2d 333, 339 (1961); *Grosjean v. Spencer*, 258 Iowa 685, 693-94, 140 N.W. 2d 139, 144-45 (1966).
- ⁶⁷Note, "Informed Consent and the Dying Patient," *op. cit.* supra n. 58 at 1638.
- ⁶⁸The medical community standard is clearly subject to great abuse. Most notably, if a physician or investigator wishes to attempt an innovative or experimental therapy and believes that full disclosure of information to the patient/subject will cause him to reject the procedure, the investigator might withhold the information and claim protection via the medical community standard rule. This effectively leaves the choice of experimental procedures and subjects up to one who has the greatest stake in seeing the whole process going forward. Note again Professor Capron's insistence on a higher disclosure standard for therapy-cum-experimentation than for pure clinical research—an implicit rejection of the medical community standard.

⁶⁹California: *Cobbs v. Grant*, 8 Cal. 3d 229, 502 P. 2d 1, 104 Cal. Rptr. 505 (1972); District of Columbia: *Canterbury v. Spence*, 150 U.S. App. D.C. 263, 464 F. 2d 772, cert. denied, 409 U.S. 1064 (1972); New Mexico: *Woods v. Brumlop*, 71 N.M. 221, 377 P. 2d 520 (1962); New York: *Fogal v. Genesee Hosp.*, 41 App. Div. 2d 468, 344 N.Y.S. 2d 552 (1973); Oregon: *Getchell v. Mansfield*, 260 Ore. 174, 489 P. 2d 953 (1971); Rhode Island: *Wilkinson v. Vesey*, 110 R.I. 606, 295 A. 2d 676 (1972); Wisconsin: *Trogan v. Fruchtmann*, 58 Wis. 2d 569, 207 N.W. 2d 297 (1973).

⁷⁰*Canterbury v. Spence*, 150 U.S. App. D.C. 263, 278 F. 2d 772, 787 (1972).

⁷¹*Id.* at 280. See also *Salgo v. Leland Stanford Jr. Univ. Bd. of Trustees*, 154 Cal. App. 2d 560, 317 P. 2d 170 at 181 (1957).

We noted here the risk that the exception to disclosure runs the risk of devouring the rule completely: "The relevant question is whether the physician acted in accordance with sound medical judgment when confronted by risk data which he could reasonably conclude would pose a substantial threat to the particular patient's well-being if disclosure were made." Waltz and Scheuneman, "Informed Consent to Therapy," *op. cit.* supra n. 59 at 643.

⁷²*Canterbury v. Spence*, 150 U.S. App. D.C. 263, 282, 464 F. 2d 772, 791 (1972).

⁷³*Id.* at 281.

⁷⁴*Cobbs v. Grant*, 8 Cal. 3d 229, 245, 502 P. 2d 1, 11-12 (1972).

⁷⁵*Id.*

⁷⁶*Wilkinson v. Vesey*, 110 R.I. 606, 625, 295 A. 2d 676, 688 (1972).

⁷⁷*Id.* at 627.

⁷⁸*Id.* at 628-29.

⁷⁹Note, "Informed Consent and the Dying Patient," *op. cit.* supra n. 58 at 1641.

⁸⁰*Id.*

⁸¹See supra n. 17.

⁸²It could perhaps best be summarized by stating that the physician is an expert in diagnosis and treatment who can best determine the desirability of a particular treatment from a medical point of view. But the patient can best assess his nonmedical needs, value preferences, future plans, religious beliefs, and capacity for pain and suffering. The different capabilities suggest the reason for focusing on the investigator's role as to disclosure of information and on the subject's role as to consent.

⁸³See Ingelfinger, "Informed (But Uneducated) Consent," 287 *New Eng. J. Med.* 465 (1972); Miller and Willner, "A Suggestion for Promoting Free and Informed Consent," 290 *New Eng. J. Med.* 464 (1974).

⁸⁴The importance of comprehension was recognized in *Canterbury v. Spence*, 150 U.S. App. D.C. 263, 271 nn. 14-15, 464 F. 2d 772, 780 nn. 14-15, cert. denied, 409 U.S. 1064 (1972).

⁸⁵Katz, *op. cit.* supra n. 2 at 609.

⁸⁶If we assume such a situation to be a true reflection of reality, this may argue *more* for Professor Capron's higher disclosure standard in the therapeutic context, since more information is required to overcome the great barriers to comprehension that may be present.

⁸⁷See Katz, *op. cit.* supra n. 2 at 610-34.

⁸⁸Fellner and Marshall, "Kidney Donors—The Myth of Informed Consent," 126 *Am. J. Psychiatry* 1245, 1250 (1970).

⁸⁹See text, section "The Case Law."

⁹⁰Then the same procedure may be employed with a parent, relative, or guardian who can give the informed consent.

⁹¹See 45 C.F.R. §46.10 (Documentation of Informed Consent).

⁹²Miller and Willner, "The Two-Part Consent Form," 290 *New Eng. J. Med.* 964 (1974).

⁹³The proposal of course does nothing to counter the other two major limitations inherent in informed consent: (a) barriers to achieving an expression of free will (impacts of unconscious motivation and subtle coercive pressure); and (b) barriers to rational decision-making (transferences, countertransferences, and psychological regressions). See generally Katz, *op. cit.* supra n. 2 at 610-73.

⁹⁴Miller and Willner, "The Two-Part Consent Form," *op. cit.* supra n. 92 at 965.

⁹⁵Who will evaluate the subject's answers? It is probably not much of a safeguard to have the investigator himself do so, in order that conflicts of interests may be minimized. If one goes outside the institution for evaluation, one runs the risk that the evaluator is not sufficiently familiar with the proposal to comment meaningfully on the subject's understanding of it. Perhaps the best solution is to find someone within the institution not connected with the project who is capable of evaluating the questionnaires. This, however, does raise conflict of interest questions of a different sort.

⁹⁶Miller and Willner, "The Two-Part Consent Form," *op. cit.* supra n. 92 at 965.

⁹⁷The second problem would alert us to the need for protective devices other than informed consent for subjects.

⁹⁸Katz, *op. cit.* supra n. 2 at 1013-52.

⁹⁹*Id.* at 955-1011.

¹⁰⁰*Id.* at 1053-1108.

¹⁰¹*Id.* at 955-1011. We could also include students, employees and those in the military.

¹⁰²*Id.* at 955.

¹⁰³There may be losses associated with the symbolic commitment as well. Yet even employing a rational, broad utilitarian calculus may lead us to value the symbolic commitment very highly, because of the irreducible core argument. In fact, those who seem to fear the application of a utilitarian model to experimental decisions as leading to an "ends justifies the means" position overlook the facts that (1) ours is not a totally unprincipled society, and (2) the legal system is designed to make extreme abuses highly unlikely, perhaps impossible, since it is oriented to deciding real cases on very particular facts. This argument is premised on "law as a system of control." See Jaffe, "Law as a System of Control," in Freund, *op. cit.* supra n. 3 at 197.

¹⁰⁴See 39 Fed. Reg. 30648 (1974) (DHEW, "Protection of Human Subjects", Proposed Policy).

¹⁰⁵See supra n. 21.

¹⁰⁶*American Medical Association Guidelines for Clinical Investigation*, *op. cit.* supra n. 21.

¹⁰⁷Burger, "Reflections on Law and Experimental Medicine," 15 *U.C.L.A. L. Rev.* 436, 438 (1968).

¹⁰⁸*Zoski v. Gaines*, 271 Mich. 1, 260 N.W. 99 (1939) (9½ years); *Moss v. Rishworth*, Tex. Com. Ap., 222 S.W. 225 (1920) (11 years); *Bonner v. Moran*, 75 U.S. App. D.C. 156, 126 F. 2d 121 (1941) (15 years); *Rogers v. Sells*, 178 Okl. 103, 61 P. 2d 1018 (1936) (14 years).

Parental consent also *assumes* that the parents have the "best interests" of the child in mind. This may not necessarily always be so (consider the battered children statistics), and we should examine this fact in each case. Again, we see a rule that is simply assumed to protect child subjects but which may not and which, with continued unquestioning acceptance, may work to discourage the search for other and better safeguards (*i.e.*, perhaps the intervention of a third party, a physician/advocate for the child, or some such arrangement. This, too, however, is not free from problems, but its virtue is a frank recognition of the dangers of unquestioned assumptions.)

- ¹⁰⁹This is for minor operations, however. *Gulf & S.I.R. Co. v. Sullivan*, 155 Miss. 1, 119 So. 501 (1928) (17 years); *Bishop v. Shurley*, 237 Mich. 76, 211 N.W. 75 (1926) (19 years); *Lacey v. Laird*, 166 Ohio St. 12, 139 N.E. 2d 25 (1956) (18 years). The reasoning is that the minor is able to comprehend the significance of the operation to himself. Then why should age ever be a factor at all? See also Restatement of Torts §59 (1939).
- ¹¹⁰Prosser, *op. cit.* supra n. 30 at 103.
- ¹¹¹*Id.*
- ¹¹²*Id.*
- ¹¹³The cases were not published in the official reports: *Masden v. Harrison*, No. 68651 Eq., Mass. Sup. Jud. Ct., June 12, 1957; *Huskey v. Harrison*, No. 68666 Eq., Mass. Sup. Jud. Ct., Aug. 30, 1957; *Foster v. Harrison*, No. 68674 Eq., Mass. Sup. Jud. Ct., Nov. 20, 1957.
- ¹¹⁴Curran, "A Problem of Consent: Kidney Transplantation in Minors," 34 *N.Y.U. L. Rev.* 891, 892 (1959).
- ¹¹⁵*Bonner v. Moran*, 126 F. 2d 121 (D.C. Cir. 1941).
- ¹¹⁶It is worth mentioning the possible existence of family pressures on the potential donor, either overt or indirect, which could effectively nullify his "freedom" to consent.
- ¹¹⁷Curran, "A Problem of Consent: Kidney Transplantation in Minors," *op. cit.* supra n. 114 at 893. Had the court based its decision on the Restatement of Torts §59 (1939), it could have completely avoided the problem of "benefit." But the Restatement would not apply to a case where the minor donor was incapable of comprehending the nature and consequences of his act (e.g., two six-year-olds, unless they happened to be child prodigies, or something approaching it).
- ¹¹⁸*Id.* at 897-98.
- ¹¹⁹*Bonner v. Moran*, 126 F. 2d 121 (D.C. Cir. 1941).
- ¹²⁰Curran and Beecher, "Experimentation in Children: A Reexamination of Legal Ethical Principles," 210 *J.A.M.A.* 77 (1969).
- ¹²¹*Id.*
- ¹²²Suppose we have a thirteen-year-old potential donor, extraordinarily intelligent, comprehending, etc., with no brothers and sisters and who wishes to donate a kidney to a very close friend, the loss of whom would have a "grave emotional impact" on the donor. Assume that the donor's parents favor the operation. According to Curran and Beecher, it would be prohibited. I suggest that this situation poses an open question that cannot be resolved simply by resort to a set of rules.
- ¹²³*Strunk v. Strunk*, 445 S.W. 145 (Ky. 1969); *Hart v. Brown*, 29 Conn. Supp. 368, 289 A. 2d 386 (1972). Contra: *In re Richardson*, 284 So. 2d 185 (La. App. 1973).
- ¹²⁴What if the fact situation were reversed? Would the court have allowed a transplant from a healthy brother to a mental incompetent with chronic kidney disease? See generally Note, "Jurisdiction—Incompetent Donor's Consent to a Kidney Transplant," 10 *Washburn L. J.* 157 (1970); Note, "A Survey of the Legal Aspects of Organ Transplantation," 50 *Chicago-Kent L. Rev.* 510 (1974).
- ¹²⁵*Strunk v. Strunk*, 445 S.W. 2d 145, 148 (1969). For more on the "doctrine of substituted judgment" see *Sherman v. Manring*, 52 Kan. 780, 107 P. 2d 741 (1940); *Sprenger v. Sprenger*, 298 Mich. 551, 299 N.W. 711 (1941).
- ¹²⁶The court also found that there would be a negligible risk to Jerry in the future of his developing problems with his one remaining kidney.
- ¹²⁷The dissent critiques the court's reasoning on this issue severely. *Strunk v. Strunk*, 445 S.W. 2d 145, 150 (1969).

¹²⁸Suppose that the psychiatric testimony established that Jerry's incompetence was of such a kind that his brother's death would *not* have affected him traumatically. Would the court then have exercised its equity powers properly to deny Tommy his brother's kidney, given the negligible risk to Jerry's present and future health? I think this hypothetical sufficiently points up the absurdity of relying on a "benefit to donor" rule to the exclusion of other factors.

¹²⁹See generally Note, "A Survey of the Legal Aspects of Organ Transplantation," *op. cit.* supra n. 125 at 510.

¹³⁰*Hart v. Brown*, 29 Conn. Supp. 368, 375, 289 A. 2d 386, 390 (1972).

¹³¹*Id.* at 369.

¹³²Martin, "Ethical Standards for Fetal Experimentation," 43 *Fordham L. Rev.* 547, 556 (1975).

¹³³*Id.*